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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,657	02/06/2002	Daniel Javitt	A8311	5724

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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/066,657	JAVITT, DANIEL	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,19,21 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *18,19,21, 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment received on 02/20/2007, wherein claims 18-19 have been amended, and new claim 46 has been added.

Applicant's amendment by deleting claim 45 is sufficient to overcome the rejection of claim 45 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Applicant's amendment by limiting to specific hydrophobic groups overcomes the rejection of claims 18, and 45 under 35 U.S.C. 102(b) as being anticipated by Takuma et al. (JP 08026986).

Applicant's amendment by limiting to specific hydrophobic groups overcomes the rejection of claims 18, 21, and 45 under 35 U.S.C. 102(b) as being anticipated by Tsai et al. (WO 99/52519, PTO-892 of record).

Claims 18-19, 21, and 46 are examined herein.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsai et al. (WO 99/52519).

Tsai et al. disclose pharmaceutical composition containing effective amounts of D-alanine, D-serine or modified version of D-alanine, D-serine or precursor of D-serine, D-alanine that is converted (e.g., metabolized) into the amino acid in vivo, such as salt, ester, alkylated form for the treatment of schizophrenia. See page 3, lines 10-16; page12, lines 26-page 13, line 30; pages 19-20, claims 1, 10, 11, 13-14. It is further disclosed that D-serine, D-alanine can be used in combination with, or in sequence with, other antipsychotics e.g., typical or atypical and depot antipsychotics for treating schizophrenia. See page 4, lines 8-24; page 7, lines 15-19. Hydrophobically modified forms of D-serine, D-alanine such as by converting the carboxy group of the amino acid to an ester group by reaction with alcohol having 1-20 carbon atoms such as methyl, ethyl, propyl, dodecyl, phenyl etc. or by alkylation of the amino group of amino acid are also disclosed. See page 13, lines 5-25. Pharmaceutical compositions for oral administration are prepared in pharmaceutically acceptable carriers such as water or other aqueous vehicles. See page 14, lines 23-30.

Tsai et al. do not explicitly teach the employment of D-serine or D-alanine compound having the particular hydrophobic groups.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the D-serine or D-alanine compounds having the particular hydrophobic groups in the prior art composition.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the D-serine or D-alanine compounds having the particular hydrophobic groups in the prior art composition, because the modified version of D-alanine, D-serine or precursor of D-serine, D-alanine that is converted (e.g., metabolized) into the amino acid in vivo have broadly covered and encompassed the particular subgenus of instant compounds are known to be useful for the treatment of schizophrenia.

Therefore, one of ordinary skill in the art would have reasonably expected that particular subgenus of instant compounds, would have same or substantially similar beneficial therapeutic effects and usefulness for the treatment of schizophrenia, based on the reasonable expectation that structurally similar species usually have similar properties. See, e.g., Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214, and If the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species, In fact, similar properties may normally be presumed when compounds are very close in structure. Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904, as noted in MPEP 2144.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsai et al., in view of Javitt (WO 97/20553, PTO-1449).

Tsai et al. as discussed above discloses pharmaceutical composition containing D-alanine or modified version of the D-alanine such as salt, ester, alkylated form for the treatment of schizophrenia. It is further disclosed that the modified version of D-alanine can be used in combination with, or in sequence with, other antipsychotics e.g., typical or atypical and depot antipsychotics for treating schizophrenia. See page 4, lines 8-24; page 7, lines 15-19.

Tsai et al. does not teach the particular modified version of D-alanine, D-alanine dodecylamide in the composition therein.

Javitt discloses a composition comprising glycyl alkyl esters, glycylalkylamides, such as glycyldodecylamide for the treatment of schizophrenia by augmenting NMDA receptor mediated neurotransmission. See page 6, lines 12-16, lines 25-27; page 9, lines 16-22; page 10, lines 15-20. It is further disclosed that glycyldodecylamide has higher potency for inhibition of glycine uptake than the esters of glycine such as glycyl ethyl ester, glycyl methyl ester, and thus more effective in treating schizophrenia. See page 17, lines 26-29. It is also disclosed that the composition comprising glycylalkyamides can be used adjunctively with antipsychotic drugs such as haloperidol, clozapine etc. See page 10, lines 1-7.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ D-alanine dodecylamide in the composition of Tsai et al. because Tsai teaches D-alanine or modified version of D-alanine can be used in the composition for treating schizophrenia, and D-alanine dodecylamide is a modified version of D-alanine. One of ordinary skill in the art at the time of invention would have been motivated to employ D-alanine dodecylamide i.e a modified version of D-alanine because Javitt teaches that the dodecylamide compounds of amino acid have higher potency than esters in treating schizophrenia. Thus, from the teachings of Tsai, and Javitt, one of ordinary skill in the art at the time of invention would have reasonable expected that a composition comprising dodecylamide compound of D-alanine, i.e D-alanine dodecylamide would have at least equal or higher potency in treating schizophrenia.

Response to Arguments:

Applicant argues that "the Declaration under 37 C.F.R. § 1.132 filed on January 13, 2006 shows that the claimed compounds provide unexpectedly superior properties, such as selectivity, which is not taught or suggested by any of the cited references. For example, in Example 3 on pages 10-11 of the present specification, treatment with D-alanine dodecylamide led to a 250% increase in specific binding to NMDA receptors and a significant trend toward increase in specific binding than under control conditions." This argument has been considered, but not found persuasive because as discussed above, from the teachings of Tsai, and Javitt, one of ordinary skill in the art at the time of invention would have reasonable expected that a composition comprising

dodecylamide compound of D-alanine, i.e D-alanine dodecylamide would have at least equal or higher potency in treating schizophrenia. Furthermore, as the combined teachings of Tsai, and Javitt renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-19, 21, and 46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-24 of Application 11/080551. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a composition comprising an effective amount of a selective D-serine transport inhibitor comprising a serine or alanine compound having a hydrophobic group for treating schizophrenia, and '551 is drawn to a composition comprising a D-serine transport inhibitor. The compositions, in the application "551 and in the instant application are seen to be substantially overlapping. Therefore, the instant claims 18-19, 21, and 45 are seen to be obvious over the claims 18-24 of application 11/080551.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Priority

Note, it is pointed out that priority to 09/365,889 is given only to the subject matter that is already disclosed in 09/365, 889.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Tuesday, Thursday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617

SHENGJUN WANG
PRIMARY EXAMINER